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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,036	09/28/2001	Dorrie M. Happ	50623.132	4580

7590

06/16/2005

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,036	HAPP, DORRIE M.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-11, 14-17, 19, 21 and 23-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/09/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Examiner acknowledges receipt of statement of common ownership, supplemental IDS, amendment to the specification, claim amendments, remarks and request for continued examination under 37 CFR 1.114, all filed 02/09/05. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/05 has been entered.

Claim Rejections - 35 USC § 112

2. The rejection of claims 2-5, 7, 15-17, 21, 23-25, 27, 32, 39, 42 and 44-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement withdrawn in light of applicant's persuasive argument.
3. The rejection of claim 26 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to the claim.

Statement of Common Ownership:

Applicant's argument regarding the rejection of claims 2-5, 7-11, 14, 19, 21, 25, 31, 36-38 and 40 as being anticipated by Harish et al. (US 2002/0122877), now US 6,503,556 is persuasive because Harish does not disclose the ratio of the light and/or UV-protecting

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compound to the polymer in the second/top coat. The statement of common ownership disqualifies Harish as art under 35 USC 103(a).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 2-5, 7-11, 14-17, 19, 21 and 23-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 6,656,506).

Wu discloses drug loaded microparticle formulation and the microparticle formulation is used to coat medical device such as balloons, stents, vascular grafts and prosthesis (abstract; column 4, lines 20-26). Some of the drugs applicable in Wu are paclitaxel, docetaxel, actinomycin-D and anticoagulants (column 3, lines 36-50). A first coating contains polymer and a drug such as actinomycin-D (Examples 1-8), which is designated as microparticle 20. A topcoat that contains microparticle 20 is applied to the first coat/layer (column 13, lines 23-34). Wu also discloses that nano-sized gold particles can also be loaded into microparticles 20 (column 8, line 66 to column 9, line 6). The gold meets the limitation of light or UV-protective compound since instant claim 11 further stipulates that gold is a light or UV-protective compound.

Wu discloses the instant claims. However, Wu does not disclose the ratio of the UV-protective compound to polymer in the topcoat. Regarding the thickness of the layer, it is not inventive to determine how thick the layer is without showing the criticality of the thickness. There is no demonstration in applicant's specification showing that certain amount of the light or

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UV-protective compound relative to certain amount of the polymer in the top-coating composition provides unusual results to the coated medical device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to coat a medical device with a coating composition that contains drug and polymer and to top-coat the initial-layers with a composition that contains drug, polymer and gold as disclosed in Wu. One having ordinary skill in the art would have been motivated to use amounts of the light or UV-protecting and polymer in mass ratios appropriate to provide the desired effect.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Llanos et al. (US 6,746,773) discloses coating composition and method of coating medical composition with the coating composition where a first layer is top coated with a top coating layer; both coating layers contain polymer and drugs (abstract; column 2, lines 25-36; column 6, lines 19 to column 8 line 21; Examples 1-8). Shanton (US 5,776,619) discloses coating composition that contains polymer and UV-protective compounds (abstract and claims 1-29).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read 'Blessing Fubara', is written over the printed name.